

### REMARKS

Claims 17-18, 20-41, 45-50, 53, 54, 70, 84-85 and 90 are pending in this application. The remaining claims have been withdrawn. Reconsideration of Claims 17, 18, 20-41, 45-50, 53, 54, 70, 84-85 and 90, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement of the statute is respectfully requested. This is the only rejection of the claims of the application. All of the rejections under 35 U.S.C. 102 and 103 have been withdrawn.

Applicant's specification has again been amended to correctly reflect the number of stable isotopes. There are in fact 252 stable isotopes in elements having two or more isotopes. In elements having more than two isotopes, there are 224 stable isotopes. These are scientific facts not debated. The specification as amended is now correct.

Each of the claims pending in this application is directed to Applicant's method of objectively identifying batched products. The broadest of the claims pending in the application are Claims 17, 45, 50 and 70, which read:

17. The method of objectively identifying batched products comprising the steps of analyzing a batched product for the concentrations of a plurality of the naturally occurring stable isotopes of said product after batching in their isotopically unaltered batched concentrations, arranging said batched concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information, indexing said product information and said readable form thereby forming an index, and maintaining said index and said product information.

45. A method of providing an objective identification of a batched product comprising the steps of analyzing a plurality of the naturally occurring stable isotopes of said batched product for their observed batched concentrations after batching in their isotopically unaltered batched concentrations, deriving empirical information from said analyzing step, and arranging said empirical information into a numerical array.

50. A method for identifying a batched composition comprising identifying a plurality of the naturally occurring stable isotopes of said batched composition, analyzing said batched composition for the batched concentrations of a plurality of the naturally occurring stable isotopes of said batched composition after batching in their isotopically unaltered batched concentrations, deriving empirical information from said analyzing step, arranging said empirical information into a numerical array and formulating said numerical array into a readable form.

70. A method of providing an objective identification of a batched product comprising the steps of analyzing a batched product after batching for the isotopically unaltered batched concentrations of a plurality of the naturally occurring stable isotopes of said batched product, arranging said batched concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information with regard to said batched product, indexing said batched product information and said readable form to a description of said product thereby forming an index, and maintaining said index and said product information and said readable form.

Each of these claims, as amended, use words in the same meaning as used in the specification, and if those words are not defined in the specification, they are used in accordance with dictionary definitions. Applicant utilizes *Webster's Ninth New Collegiate Dictionary* as well as the Examiner. Applicant sincerely thanks the Examiner for directing his attention specifically to the dictionary definitions of "anthropogenically unaltered" language and the "naturally occurring" language as used in the claims. The words "anthropogenically unaltered" have always been used to modify Applicant's observed batched "concentrations" after batching and upon isotopic analysis. The words "anthropogenically unaltered" have not been used by Applicant to modify any other word or unbatched concentration. The Examiner is absolutely correct in suggesting that any concentration that is "anthropogenically unaltered" is not altered after batching by a human being or by any chemical process. Similarly, Applicant uses the term "naturally occurring" solely as a modifier of Applicant's "stable isotopes" to refer to those stable isotopes - as opposed to chemical compounds which occur in nature. Applicant does not use the

words "naturally occurring" to modify Applicant's "batched products" or "batched concentrations or anything else. The Examiner is correct that no where in the specification are these terms defined differently than the dictionary definitions found by the Examiner. As used in Applicant's claims, these terms, as well as the definition of "batched product" appearing on page 8 of Applicant's specification are not varied from the definitions found in Applicant's specification or in the Examiner's dictionary. For clarify, Applicant has amended the claims to use the words "isotopically unaltered" instead of the words "anthropogenically unaltered."

Referring to Claim 17, the term "batched product" is exactly as identified on page 8 of Applicant's specification. Thus, most of the batched products are not "naturally occurring." In fact, prior to the "step of analyzing a batched product," the batched product may have been synthetically created, or undergone many kinetic or other isotope effects, and thus be anthropogenically altered in a variety of different ways prior to the product identifying, final and thus the only relevant batching step. Applicant's process is only concerned with what happens to the batched product after this batching and not before batching as the batching referred to in Applicant's claims identifies that product which later will be identified by Applicant's process.

The step of "analyzing a batched product for the concentration of a plurality of the naturally occurring stable isotopes of said batched product after batching in their anthropogenically or isotopically unaltered batched concentrations is then performed in accordance with Applicant's method. The analysis is conducted on "said batched product" and the analysis is conducted to determine the observed concentrations of a plurality of the naturally occurring isotopes "of said batched product." While the word "observed" is not used in all of Applicant's claims as it is somewhat redundant (analyzing a batched product for the

concentration is no different than analyzing a batched product for the observed concentration), Applicant would insert "observed" into the claims if that would place the claims in allowable form. If amending the claims in this way would place the application in allowable form, all the Examiner needs to do is to telephone Applicant's attorney and Applicant's attorney will file an amendment supplemental to this Amendment amending the claims in that respect. Otherwise, Applicant prefers not to insert the word "observed" into all of the claims as it may be later misinterpreted by others.

Thus, what is analyzed is "a batched product" and the analysis step is performed on the "stable isotopes of said batched product after batching." All of the stable isotopes of every one of Applicant's batched products are naturally occurring stable isotopes. Applicant is not making any analysis for the isotopes of any elements which are not listed on the periodic table as amended from time to time as new elements are discovered. Further, the analysis is made on the "naturally occurring stable isotopes of said batched product after batching in their isotopically unaltered batched concentrations." Once the batched product is identified in accordance with Applicant's method, there cannot be any measurable anthropogenically or isotopically alteration of the isotope concentrations of the batched product. Thus, once the batched product is identified, the batched product will not be isotopically altered prior to conducting the analyzing step. Otherwise, the observed concentrations resulting from the analyzing step will be of a product different than the batched product.

Similarly, the batched product cannot be anthropogenically or isotopically altered between its analysis and Applicant's comparison step. If such alteration occurs, then, Applicant's method will not identify an unknown composition as the originally selected batched

product because the batched product compared to the unknown product is indeed a different product, isotopically, although you could make a good case that the compared product and the batched product are the same or related if only one of ten isotopes analyzed are changed by a kinetic effect and all of the other nine are identical.

It does not take a rocket scientist to understand this concept, nor even an analytical chemist. Common ordinary people, if they were utilizing an identification method such as Applicant's in a mechanical (not chemical) sense to identify washers from a batch of washers, it would be readily understood that the washers would have only three physical properties (leaving out the composition from which the washers are made) to compare, i.e., the outside diameter, the inside diameter of the hole in the washer, and the thickness of the washer. If between "batching" and the analysis step, i.e., measuring the two diameters and the thickness, or between the analysis step and the comparing step the washers are "anthropogenically altered" by either changing the thickness of the washer or reaming out the hole to increase the diameter, even uneducated people would know that the comparison step would not identify the anthropogenically altered washers to be a part of the original batch of washers.

As the Examiner understands however, Applicant's batched product, once identified, could be batched and rebatched between the identification of the batched product and the "analyzing a batched product for the concentration of a plurality of the naturally occurring stable isotopes of said batched product" without affecting Applicant's method, and could be batched and rebatched between Applicant's analysis and the comparing steps without affecting Applicant's process so long as no isotopic alteration of Applicant's compositions occur. In fact, such rebatching occurs in the performance of Applicant's process routinely. However,

Applicant's process will not work if the batched product, after batching, is isotopically altered except as above noted.

All persons skilled in the art to which Applicant's invention relates and to whom Applicant's specification and claims are directed are totally familiar with the examples of isotopic alteration.

Applicant would like to apologize for the confusing language found on page 13 of Applicant's response dated January 25, 2005, and any language expressly or impliedly indicated that the word "naturally" does not refer to "as in nature." Additionally, Applicant would like the Examiner to disregard any such language appearing in any of the prosecution history in which the term "naturally occurring" may be suggested to modify Applicant's "batched product," "composition," or "concentration," which may have lead to the Examiner's confusion. Applicant's has used the term "naturally occurring" in the claims only to modify the words "stable isotopes," nothing else. Similarly, Applicant has only used the term "anthropogenically unaltered" to refer to Applicant's observed concentrations of the naturally occurring stable isotopes of Applicant's "batched product after batching" and previous to isotopic analysis to refer to an isotope concentration that has not been altered "after batching." Nothing else should be inferred by Applicant's language during the prosecution of this application.

As stated before, it is not surprising that the Examiner has read through the specification and was unable to find any discussion of an anthropogenically unaltered isotope concentration method as Applicant's specification does not utilize the language "anthropogenically unaltered" to refer to the isotopic concentrations after batching or the words "naturally occurring" to refer to the stable isotopes of a batched product. Since Applicant's method starts with a batched product

that has a plurality of naturally occurring stable isotopes in their unaltered concentrations and proceeds with the step of analyzing for the concentration of a plurality of the "naturally occurring" stable isotopes, there was no reason for Applicant to discuss such batched products in the specification. Similarly, it is clear to all that in an identification method which includes a comparing step between a batched product and an unknown product, alteration of the observed concentrations of the batched product would mean that Applicant would never identify an unknown product.

In accordance with each of Applicant's claims, once the observed concentrations of "said naturally occurring stable isotopes of said batched product" are determined, each of the claims requires them to be arranged into a mathematical or numerical array, Claims 17, 50 and 70 require that mathematical array to be formulated into a readable form, and Claims 17 and 70 require the readable form to be indexed with a description of the product and for the index to be maintained. In both Claims 45 and 50, the observed concentrations derived from analyzing the batched product may be assembled into a readable form utilizing other imperical information in addition to the observed concentrations. In the entire prosecution of this application, the Examiner has never formulated any rejection related to Applicant's formulating, assembly, maintaining, deriving, arranging, or indexing steps. Thus, these steps will not be discussed further.

For all of the reasons given above and the fact that the terms "naturally occurring" or "anthropogenically unaltered" are not defined in the specification and thus relies on dictionary definitions, Applicant respectfully submits that all of the language in Applicant's claims is allowable under 35 U.S.C. §112, paragraphs 1 and 2. All of the language of the claims is

supported by the specification. All of the language of the claims is definite and particularly points out and distinctly claims the subject matter which Applicant regards as his invention. Applicant respectfully submits that the rejection under 35 U.S.C. §112 should be withdrawn.

Claims 18, 20, 21, 41, 49, 53, 54, and 84 are each dependent upon Claim 17, thus each of these claims include all of the limitations of Claim 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 18 further requires:

“the step of measuring the observed concentration of one or more of said isotopes in a comparable substance and comparing the concentration of said one or more isotopes of said comparable substance with the concentrations of said mathematical array in readable form to identify said substance.”

Claim 20 further requires:

“said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof.”

Claim 21 further requires:

“said readable form is a machine readable form of said mathematical array, said product information is placed on a machine, said machine readable form being indexed to said product information.”

Claim 41 further requires:

“said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error



added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof."

Claim 49 further requires:

"the step of increasing the composition of at least one of the plurality of stable isotopes of said composition prior to hatching, and analyzing the same as part of said analyzing step."

Claim 53 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia."

Claim 54 further requires:

"the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes."

Claim 84 further requires:

"said analyses of said analyzing steps each have a dynamic range equal to the observed range divided by the 1-sigma standard deviation."

Claims 22 and 24 are dependent upon Claims 21 and 17, thus Claims 22 and 24 include all of the limitations of Claims 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 21 and 17. Claim 22 further requires:

"said product information may be displayed by identifying said machine readable form and indexing the same to said product information."

Claim 24 further requires:

"measuring the observed concentrations of said isotopes in a

comparable substance, arranging said comparable substance concentrations into a mathematical array, and comparing the mathematical array of said comparable substance with said mathematical array of said product."

Claim 23 is dependent upon Claims 22, 21, and 17, thus Claim 23 includes all of the limitations of Claims 22, 21, and 17 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 22, 21, and 17. Claim 23 further requires:

"said product information may be scrolled and/or downloaded or printed as desired."

Claims 25-33, 36 and 37 are each dependent upon Claims 24, 21, and 17, thus Claims 25-33, 36 and 37 each include all of the limitations of Claims 24, 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 24, 21, and 17. Claim 25 further requires:

"said mathematical array includes ratios and concentrations and said comparing step comprises comparing each of said ratios and concentrations step by step to identify said comparable substance within the error desired."

Claim 26 further requires:

"said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors."

Claim 27 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia."

Claim 28 further requires:

"said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a

plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof."

Claim 29 further requires:

"the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes."

Claim 30 further requires:

"said isotopes are of any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof."

Claim 31 further requires:

"the error of identification is chosen by the mathematical array chosen, the number of concentrations of isotopes utilized in said array, and the portion of said array compared with the isotopic analysis of said unknown product."

Claim 32 further requires:

"the batched product from which the concentrations of isotopes are analyzed and formed into a mathematical array is chosen from the group of batched products consisting of active pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials and drug products, combustible fuels, additives to combustible fuels, environmental and natural occurring products, explosives and ammunition, gun powder, crude oil, petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings, and other synthetic materials."

Claim 33 further requires:

"said concentrations of isotopes are chosen from the group of concentrations of isotopes consisting of bulk phase analysis and specific compound analysis."

Claim 36 further requires:

"said analyses include nuclear magnetic resonance."

Claim 37 further requires:

"said readable form is a machine readable form and said product information is stored in memory on a machine together with the index, said machine readable form, index and product information being interlinked, said machine readable form once identified through the index presents stored product information in displayed form."

Claims 34 and 35 are each dependent upon Claims 33, 24, 21, and 17, thus Claims 34 and 35 each include all of the limitations of Claims 33, 24, 21, and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 33, 24, 21, and 17.

Claim 34 further requires:

"said bulk phase analysis includes off-line dual inlet isotope ratio mass spectrometry (irMS) and on-line combustion coupled with high resolution isotope ratio monitoring/mass spectrometry (irmMS)."

Claim 35 further requires:

"specific compound analysis includes gas chromatography coupled with irMS (irmGCMS) and liquid chromatography coupled with irMS (irmLCMS)."

Claims 38-40 are each dependent upon Claims 37, 24, 21, and 17, thus Claims 38-40 each include all of the limitations of Claims 37, 24, 21, and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 38 further requires:

"said product information may be scrolled through."

Claim 39 further requires:

"said product information may be printed."

Claim 40 further requires:

"said product information may be accessed through said index from said machine readable form of said mathematical array."

Claim 46 is dependent upon Claim 45, thus Claim 46 includes all of the limitations of Claim 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claim 45. Claim 46 further requires:

"said analyzing step comprises determining observed ratios of said measured batched concentrations of two or more stable isotopes of said batched product."

Claim 47 is dependent upon Claims 46 and 45, thus Claim 47 includes all of the limitations of Claims 46 and 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 46 and 45. Claim 47 further requires:

"the steps of performing the method of Claim 46 for a plurality of known compositions, indexing said numerical arrays for said known compositions in a readable form into an index linking said numerical arrays to product information for a plurality of known compositions, performing the method of Claim 46 for said unknown composition, comparing said numerical array for said unknown composition to said numerical arrays of said index, determining whether said numerical array for said unknown composition matches any of the numerical arrays contained in said index, and attempting to match said numerical array of said unknown composition to the numerical array of a known composition in said index thereby identifying said unknown composition or distinguishing said unknown composition from said known compositions of said index."

Claim 90 is dependent upon Claims 84 and 17, thus Claim 90 includes all of the

limitations of Claims 84 and 17 and is submitted to be allowable for the same reasons as reiterated above with regard to Claim 17. Claim 90 further requires:

"the dynamic range is the range of values expected for an analysis divided by the 1-sigma standard deviation of that analysis."

The amendments made herein merely adopt the Examiner's suggestions, remove issues for appeal and requires only a cursory review by the Examiner. This amendment places all of the claims pending in form for immediate allowance. No new matter has been added; no new issues have been raised.

Applicant has carefully examined each of the amended claims in this application and compared the same with the claims as filed. All of the claims that have been amended have either been amended to broaden the scope of the claims, correct spelling or the grammar, or more particularly and distinctly define terms appearing in the claims as originally filed in accordance with 35 U.S.C. 112.

For all of the reasons above given Applicant respectfully submits that each of the claims of the application, as amended, patentably distinguish Applicant's invention from the patents cited and/or applied by the Examiner, whether taken alone or in combination with each other. Applicant respectfully solicits a prompt issuance of a Notice of Allowance.

Respectfully submitted,

David A. Lundy  
Reg. No. 22,162